K083350

Section B – 510(K) Summary

Date Summary Was Prepared: November 11th, 2008

Submitter's Information:

APR 21 2009

Covidien, LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000

Contact:

Wei Zhao
Manager, Regulatory Affairs
Covidien, LP
Telephone: 508-261-8404
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Device Trade Name: Superior Starburst Reusable Self-adhering TENS/NMES/FES Stimulating Electrodes

Device Common Name: Cutaneous Electrode

Classification Panel: Neurology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The proposed Covidien Superior Starburst Reusable Self-adhering TENS/NMES/FES Stimulating Electrodes are substantially equivalent to the currently marketed Covidien Reusable Self-adhering TENS/FES/NMES Stimulating Electrodes in intended use, physical characteristics, and performance characteristics. The predicate device is classified as Class II device.

Device Description:

The proposed electrode composes of a top cover, a reinforcement film, a conductive member with printed Silver, conductive hydrogel which contains Aloe Vera and green pigment, a release liner which protects the conductive hydrogel before use and during storage, and a wire secured in between reinforcement film and conductive member. The wire connects the electrode to the transcutaneous electrical stimulation devices. Four finished electrodes are placed into a protective pouch. The pouches are sealed and boxed for shipping.

Intended Use:

The Superior Starburst Reusable Self-adhering TENS/NMES/FES Stimulating Electrodes are indicated for use with transcutaneous electrical stimulation devices as non-sterile, Latex free, reusable device for single patient use only. The electrodes provide the conductive interface

between the stimulation device and the patient's skin. The starburst gradient pattern provides optimal current distribution.

Performance Data:

Performance data for the proposed electrodes are compared to that of the predicate device. Results from biocompatibility study, physical and functional performance evaluation demonstrate that the proposed device is substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2009

Covidien, LP
% Ms. Wei Zhao
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K083350
Trade/Device Name: Superior Starburst Reusable Self-adhering Stimulating Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: April 9, 2009
Received: April 13, 2009

Dear Ms. Zhao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):K083350

Device Name:

Superior Starburst Reusable Self-adhering TENS/NMES/FES Stimulating Electrodes

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Prescription Use ___X___ And/Or Over the Counter Use ___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083350